MAXIMUS Federal Services

Case Number:	CM15-0214298		
Date Assigned:	11/04/2015	Date of Injury:	05/04/2010
Decision Date:	12/24/2015	UR Denial Date:	10/23/2015
Priority:	Standard	Application Received:	10/30/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: California, District of Columbia, Maryland
Certification(s)/Specialty: Anesthesiology, Pain Management

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 52 year old female with an industrial injury date of 05-04-2010 and 07-27-2012. Medical record review indicates she is being treated for status post left knee arthroscopy, right knee patellofemoral arthralgia, left ankle sprain, bilateral wrist sprain and bilateral hip greater trochanteric bursitis. On 09-21-2015 the injured worker presented with complaints of bilateral knee pain, bilateral wrist pain, left ankle pain and bilateral hip pain. Work status is documented as modified work. Prior treatment included physical therapy, injection to knee and surgery. Physical exam (09-21-2015) of bilateral knees revealed distal thigh and calf of the left lower leg was greater in circumference than the right distal thigh and calf. There was tenderness to palpation over the medial joint line and medial tibial condyle of the left greater knee greater than the lateral joint and peri patellar region. There was crepitus upon passive range of motion of the left knee with positive Grind test on the left. There was tenderness to palpation over the medial and lateral joint lines and peri patellar region of the right knee. Right knee flexion was 130 degree and extension was 0 degrees. Range of motion of the left knee was 125 degree flexion and 0 degrees extension. On 10-23-2015 the request for the following treatments was non-certified by utilization review:-Synvisc injections to the left knee (series of three (3) 2 ml each, total of 6 ml or 48 mg).-Left knee Bioni Care system with lateral unloader brace with OActive brace.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Synvisc injections to the left knee (series of three (3) 2ml each, total of 6ml or 48mg): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Knee and Leg Chapter - Hyaluronic acid injections.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg, Hyaluronic Acid Injections.

Decision rationale: The MTUS is silent on the use of hyaluronic acid injections. Per ODG TWC with regard to viscosupplementation, hyaluronic acid injections are "Recommended as a possible option for severe osteoarthritis for patients who have not responded adequately to recommended conservative treatments (exercise, NSAIDs or acetaminophen), to potentially delay total knee replacement, but in recent quality studies the magnitude of improvement appears modest at best. While osteoarthritis of the knee is a recommended indication, there is insufficient evidence for other conditions, including patellofemoral arthritis, chondromalacia patellae, osteochondritis dissecans, or patellofemoral syndrome (patellar knee pain)." Criteria for Hyaluronic acid injections: Patients experience significantly symptomatic osteoarthritis but have not responded adequately to recommended conservative nonpharmacologic (e.g., exercise) and pharmacologic treatments or are intolerant of these therapies (e.g., gastrointestinal problems related to anti-inflammatory medications), after at least 3 months; Documented symptomatic severe osteoarthritis of the knee, which may include the following: Bony enlargement; Bony tenderness; Crepitus (noisy, grating sound) on active motion; Less than 30 minutes of morning stiffness; No palpable warmth of synovium; Over 50 years of age. Pain interferes with functional activities (e.g., ambulation, prolonged standing) and not attributed to other forms of joint disease; Failure to adequately respond to aspiration and injection of intra-articular steroids; Generally performed without fluoroscopic or ultrasound guidance; Are not currently candidates for total knee replacement or who have failed previous knee surgery for their arthritis, unless younger patients wanting to delay total knee replacement. (Wen, 2000) Repeat series of injections: If documented significant improvement in symptoms for 6 months or more, and symptoms recur, may be reasonable to do another series. No maximum established by high quality scientific evidence; see Repeat series of injections above. Hyaluronic acid injections are not recommended for any other indications such as chondromalacia patellae, facet joint arthropathy, osteochondritis dissecans, or patellofemoral arthritis, patellofemoral syndrome (patellar knee pain), plantar nerve entrapment syndrome, or for use in joints other than the knee (e.g., ankle, carpo-metacarpal joint, elbow, hip, metatarso-phalangeal joint, shoulder, and temporomandibular joint) because the effectiveness of hyaluronic acid injections for these indications has not been established. The documentation submitted for review does not contain any recent diagnostic reports showing degenerative changes or evidence of severe osteoarthritis. There is no evidence of failure to respond adequately to aspiration and injection of intra-articular steroids. The request is not medically necessary.

Left knee BioniCare system with lateral unloader brace with OActive brace: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Knee and Leg Chapter - BioniCare knee device.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee & Leg, BioniCare knee device.

Decision rationale: Per the ODG guidelines regarding the BioniCare knee device: Recommended as an option for patients in a therapeutic exercise program for osteoarthritis of the knee, who may be candidates for total knee arthroplasty (TKA) but want to defer surgery. See also TENS (transcutaneous electrical nerve stimulation). This device received FDA approval as a TENS device, but there are additional claims of tissue regeneration effectiveness and studies suggesting the possibility of deferral of TKA with use of the BioniCare device. Compared with TENS there are differences in the electrical signal (having a monophasic pulsed time varying waveform versus biphasic with TENS), electrical stimulus (having signal strengths that the patient cannot detect), FDA indications for use (includes overall improvement of knee osteoarthritis), mechanisms of action (includes cartilage stimulation), onset and duration of action (analgesia is delayed but the effect persists longer), route of administration (only for use overlying the osteoarthritic knee), hours of use (6-10 hours/day while sleeping, versus 10-30 minutes/day for TENS). The higher quality studies are summarized below. Improvements in clinical measures for pain and function found in this study suggest that pulsed electrical stimulation using the Bionicare device is effective for treating OA of the knee. (Zizic, 1995) After 4 years 65% of the Bionicare group had deferred TKA verus 35% of the group with no treatment, but the Bionicare cohort may have delayed surgery because they were instructed by a nurse practitioner to use the Bionicare device for 8 hours per day, suggesting that it would be a cure. (Mont, 2006) The Bionicare device successfully attenuated knee OA symptoms in patients who had failed non-surgical therapy. Less than 250 hours of therapy provided relief, but improvement increased in a dose-response manner after 750 hours of cumulative use. (Farr, 2006) Bionicare treatment provided superior outcomes between baseline and 3-month follow-up measurements. The percent of patients who improved by more than 50% was 38.5 active vs 5.3 placebo in patient global, 43.6 vs 15.8 in patient pain, and 23.1 vs 5.3 in total WOMAC. (Garland, 2007) The documentation submitted for review does not indicate that the injured worker is participating in a therapeutic exercise program or is a candidate for total knee arthroplasty. As there is no indication for the device, the request is not medically necessary.